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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,268	03/29/2004	Jeffrey William Moehlenbruck	2103.013882/SBI-064-DIV	2977

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,268	MOEHLENBRUCK ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *82-102 and 125* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *82-102 and 125* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This Office action is in response to Applicants' remarks received July 6, 2007. Claims 1-81, 103-124 are canceled. Claims 82-102, 125 are pending and currently under examination.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Priority: The priority date is April 7, 2000.

The declaration filed on July 6, 2007 under 37 CFR 1.131 is sufficient to overcome the Ferree reference (US 6352557).

Objections and Rejections

Claims 84-90, 92-93, 95 are objected to because of the following informalities: the instant claims recite "portion". It is unclear which portion of the nucleus pulposus tissue the claims are referring to. Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 82-88, 91-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mechanic (US 5854397; previously cited) in view of Gan et al. (US 5964807).

Mechanic discloses a process for cross-linking a proteinaceous material, including collagen, collagen fibrils, and collagen matrices (col. 4 lines 15-16). According to Mechanic, the term proteinaceous material includes both proteins such as collagen and protein-containing materials such as tissue (col. 4 lines 19-20). Proteinaceous materials soaked in a first media solution and irradiated in a second are better cross-linked, show improved mechanical properties and decreased susceptibility to proteolytic degradation (col. 5 lines 1-4). Mechanic discloses solutions of high osmolality are generally used for the first media solution, i.e. sodium, chloride, potassium buffers, and Good's buffers, where in the osmolality have been increased by addition of a solute, such as sucrose (col. 5 line 10). In working examples 1-10, Mechanic discloses proteinaceous materials from different sources to be crosslinked, including pericardium tissue, collagen fibrils, and collagen (col. 8-13). In example 8, rat type I collagen was divided into six samples and each sample was placed in a dialysis bag with 300 mg NaCl (col. 12 line 35-37). Samples 5-6 were dialyzed into phosphate buffered saline pH 7.4 including 50% sucrose, and 0.2% methylene blue (col. 12, lines 40-41) and then exposed to a white floodflight while holding the temperature between 8° and 12°C (col. 12, lines 45-50). Mechanic does not teach nucleus pulposus tissue or an intervertebral disc regenerating material.

Gan et al. disclose a hybrid material comprising intervertebral disc cells and a biodegradable support substrate for implantation into the intervertebral disc space (col. 5 lines 42-44). To prepare the hybrid material, intervertebral disc cells are combined with biodegradable substrate materials, i.e. polymer foams (col. 7 lines 11-20, lines 65-66). The intervertebral disc cells are nucleus pulposus cells extracted from the nucleus pulposus of lumbar discs, sacral discs, or cervical discs (col. 8 lines 1-7). Gan et al. further disclose the cells may be

obtained from the patient being treated or may be extracted from donor tissue (col. 8 lines 8-9) by surgical techniques (col. 8 lines 39-44). The extracted nucleus pulposus tissue can be treated with enzymes to disaggregate the cells (col. 8 lines 50-51). Further, the hybrid material can also include factors to enhance cell growth, i.e. TGF-β, EGF (col. 8 lines 62-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to manufacture an intervertebral disc implant by modifying the teachings of Mechanic and substituting the nucleus pulposus hybrid material of Gan et al. for the collagen (fibrils) used in Mechanic (claims 82-88, 91-100). The motivation to do so is given by Gan et al., which teach a hybrid material comprising a biodegradable substrate material and nucleus pulposus cells can be implanted into a recipient to treat intervertebral disc collapse, and Mechanic, which teaches that cross-linking tissue and/or collagen results in a stable, bio-product that resists in vivo degradation and calcification when implanted.

It would also have been obvious to one of ordinary skill in the art at the time the invention was made to add an additional therapeutic substance, i.e. TGF-β, to the disc implant manufactured by the method of Mechanic in view of Gan et al. (claims 101-102, 125). The motivation to do so is given by Gan et al., which teach that additional therapeutic substances can be added to the nucleus pulposus hybrid implant and may enhance growth of intervertebral disc cells in the recipient.

Claims 89-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mechanic (US 5854397; previously cited) in view of Gan et al. (US 5964807) in view of Moore et al. (US

6350732; IDS). The teachings of Mechanic and Gan et al. are outlined above. Neither Mechanic nor Gan et al. teach extracting lipids from a collagenous tissue sample.

Moore et al. teach a method for extracting lipids from collagenous tissue samples for the purpose of storing and preserving the tissue sample and the product of that method (col. 1 lines 29-35).

It would have been obvious to one of ordinary skill in the art to extract lipids from the nucleus pulposus matrix manufactured by the method of Mechanic in view of Gan et al. (claims 89-90). The motivation to do so is given by Moore et al., which teach that extracting lipids from collagenous tissue samples will allow the product to be better preserved and stored for longer periods of time. One of ordinary skill would recognize that nucleus pulposus cells and/or tissue that are better preserved would cause less complications when implanted in the body.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

September 13, 2007

M. Monshipouri
MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER